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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/533,183                  | 04/28/2005  | Keita Nishino        | 5404/104            | 4461             |
| 757                         | 7590        | 09/06/2007           | EXAMINER            |                  |
| BRINKS HOFER GILSON & LIONE |             |                      | BERCH, MARK L       |                  |
| P.O. BOX 10395              |             |                      | ART UNIT            | PAPER NUMBER     |
| CHICAGO, IL 60610           |             |                      | 1624                |                  |
| MAIL DATE                   |             | DELIVERY MODE        |                     |                  |
| 09/06/2007                  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/533,183             | NISHINO ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | /Mark L. Berch/        | 1624                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-4 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/25/07;5/23/07;4/28/05.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5414081 alone, or alternatively Sakurai or US 5414081 in view of EP 188816 or US 5578722.

In Sakurai, see the conversion of 18 to 19 in scheme 4. This corresponds to the claimed reaction, in which R2 is t-butyl; diisopropylethylamine was used as base.. The sole difference is that the claims call for the trimethylsilyl protecting group, and the prior art has the t-butyldimethylsilyl protecting group. This is a very small difference; both are trialkylsilyl protecting group, and are protecting an OH group at a remote point – i.e. not at the reacting site.

Similarly, in US 5414081, see step (4) of example 6, which basically has the same teaching, albeit with a different thiol being reacted.

First, US 5414081 teaches that the protecting group can be triloweralkylsilyl, see column 2, lines 59-60. Since trimethylsilyl is the simplest triloweralkylsilyl, that would be understood by one of ordinary skill in the art as an alternative to the t-butyldimethylsilyl used in the example. In addition, for the R4=H option in the rejected claims, the definition

of R1 in the reference includes the unprotected OH, i.e. it says that the OH "may be protected". Thus, the reference alone renders obvious the use of the unprotected OH or the OH protected by trimethylsilyl.

In addition, the secondary reference establish that the art considers the two to be alternatively useable in the reaction. Page 23 (IX) to (VII) shows the general reaction here. X' is taught as a protected OH group (page 14, lines 1-2). L is taught as the active ester of an OH group (page 21, lines 12-13), and specifically, the active ester of diphenylphosphoric acid, i.e. the exact one used here is taught at 10<sup>th</sup> and 9<sup>th</sup> from last line of page 21. Page 3, lines 9-10 teaches exactly two choices for silyl protecting groups, viz, the trimethylsilyl protecting group of the claims, and the t-butyldimethylsilyl of the primary references, establishing the two as equivalent. Indeed, example 13 shows the use of the trimethylsilyl protecting group. The exact details are not given at that point, but the example refers to example 11-3, which in fact has the t-butyldimethylsilyl group, against emphasizing the fact that these are alternatively used. Example 11-3 is applicant same overall process. The cyclization, and phosphorylation correspond to what appears in this specification, page 21, second step. Indeed, the reagent used in example 11-3, diphenylchlorophosphate, and used by applicants in reference example 3, is the same, albeit the compound is named differently. This is then reacted with the thiol, as seen on page E-58 of the reference.

In addition, the reference clearly teaches that the displacement with the tiol can be done with the OH unprotected (note that R4 in claim 1 can be H). See page E-51

A similar teaching appears in 5578722, this time for the triethylsilyl group. The overall reaction is seen in column 48, IV to III to V. X is a protected OH group, and three trialkyl silyl groups are named at column 3, lines 5-7: trimethylsilyl group, triethylsilyl

group, and t-butyldimethylsilyl group. This again establishes that these are considered alternatively useable. L is again taught as the active ester of an OH group and specifically, the active ester of diphenylphosphoric acid (column 5 line 7). The use of the triethylsilyl group is seen in example 7.

Thus, in this circumstance, applicants have substituted one known element (a protecting group) for another of the same function. This element, and its function have thus been shown to be known in the art. One of ordinary skill in the art could have substituted one known element for another, and the results would have been predictable, as that is precisely the teaching of the secondary reference. There is a reasonable expectation of success, since success was indeed achieved with the alternative element (the trimethylsilyl protecting group) in the secondary references. Note *In re Fout*, 213 USPQ 532; *In re O'Farrell*, 7 USPQ2d 1673, *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "general" is not correct; a formula cannot be both general and specific. Deletion of the word is suggested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

8/31/2007